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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Paul D. Corl

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EXAMINER

TOTH, KAREN E

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/658,926		CORL ET AL.	
	Examiner		Art Unit	
	KAREN E. TOTH		3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-29 and 56-73 is/are pending in the application.
- 4a) Of the above claim(s) 66 and 67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-29, 56-65, 68-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

2. Claims 25, 26, 28, 29, 63, 64, 68, and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel (US Patent Application Publication 2003/0050547) in view of Markle (US Patent 5596988) and Webber (US Patent 6616614).

Regarding claim 25, Lebel discloses a probe comprising a cannula (element 12) with proximal (element 14) and distal (element 18) extremities, where the distal extremity is adapted to be inserted in a patient's blood vessel (paragraph [0030]) and contains an oxygen sensor assembly that provides an electrical signal when the cannula is disposed in the blood (element 20; paragraphs [0030], [0032]), and where the proximal extremity carries a connector (element 16); the distal extremity is adapted to slidably travel through an introducer when being inserted into the vessel (figure 9; step 110; paragraphs [0058]-[0059]), and the cannula and connector are sized such that the introducer may be slid off the proximal extremity and cannula after the distal extremity has been inserted (figure 9; step 112; paragraphs [0058]-[0059]). The Examiner notes that, though an introducer is mentioned in the claim, it is not actually part of the claimed apparatus, and the probe of Lebel merely needs to be able to work with any device used as an introducer. Lebel does not disclose a preferred diameter range for the cannula, a carbon dioxide sensor in addition to the oxygen sensor, or the

Art Unit: 3735

sensor assembly comprising a tube and proximal and distal sensors where the proximal sensor comprises an electrode extending around the tube and the distal sensor passing through the tube.

Markle teaches a probe for ascertaining characteristics of blood comprising a cannula having a diameter between 0.010 and 0.035 inches (column 5, lines 62-63), and a plurality of gas sensors, including those for carbon dioxide and oxygen in the distal extremity of the cannula (column 6 lines 1-3), in order to accurately monitor a patient's blood characteristics in small vessels.

Webber teaches a sensor assembly for ascertaining blood characteristics comprising a distal sensor and conductor (element 81) within a tube (glass insulation - column 5, lines 32-35) and a proximal sensor extending around the tube (element 82; figure 11), in order to conserve space in the device.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel with an additional gas sensor for oxygen and sized the system to have an external diameter between 0.010 and 0.035 inches, as taught by Markle, in order to monitor multiple components of blood in small vessels, and further including a distal sensor and conductor within a tube and a proximal sensor extending around the tube, as taught by Webber, in order to conserve space in the device.

The Examiner notes that, in the specification of the present application, it appears that one of the proximal and distal sensors is the carbon dioxide sensor, and the other is the oxygen sensor. However, the claim is directed merely to an assembly

Art Unit: 3735

comprising unspecified sensors, which means that any combination of additional sensors (such as Webber's working and reference sensing electrodes) may be included.

Regarding claim 26, Lebel further discloses using an introducer with the device (paragraphs [0058]-[0059]).

Regarding claims 28 and 29, Lebel further discloses the connector having a cylindrical portion (figure 1) and an electrical contact (paragraph [0031]), and the probe having a conductor extending from the electrical contact to the sensor and seated flush with the cylindrical portion (element 62; paragraphs [0042] and [0046]).

Regarding claims 63 and 64, Lebel discloses using gas-permeable material to form the cannula (element 66; paragraphs [0044], [0054]).

Regarding claims 68 and 69, Lebel in view of Markle and Webber discloses all the elements of the claimed invention, as described above, except for the system further comprising a display module with a connector for connecting to the probe's connector, allowing communication between the probe and display, and where the display module includes a band that makes it adaptable for securing to a patient's wrist.

Webber further teaches a display module (element 22) that connects to and communicates with the implantable blood probe (elements 23, 24, 51), and comprises a band (element 28) that allows the display to be mounted on the patient's arm in a location of the user's choosing, such as the wrist (figure 1), in order to provide as much mobility to the patient as possible while still accurately monitoring the blood gas. It would have been obvious to one of ordinary skill in the art at the time the invention was

Art Unit: 3735

made to have made the system of Lebel in view of Markle and Webber with a display module connected to the connector of the probe and secured to the patient's wrist, as taught by Webber, in order to provide mobility while monitoring blood gas.

3. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle and Webber, as applied to claims 25, 26, 28, 29, 63, 64, 68, and 69 above, and further in view of Schulman (US Patent 5497772).

Lebel in view of Markle and Webber discloses all the elements of the claimed invention, as described above, except for the introducer being a needle. Schulman teaches a system for implanting a blood component sensor comprising an introducer needle that is used to place a sensor probe (column 10, lines 10-24), in order to ease the insertion of the sensor. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel in view of Markle and Webber with an introducer needle, as taught by Schulman, in order to ease insertion of the sensor.

4. Claims 56-58 and 60-61 rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle and Webber, as applied to claims 25, 26, 28, 29, 63, 64, 68, and 69 above, and further in view of Cheney (US Patent 5391250).

Regarding claim 56, Lebel in view of Markle and Webber discloses all the elements of the claimed invention, as disclosed above, except for the probe comprising

Art Unit: 3735

a flex circuit extending through the cannula, having a distal portion with two electrodes, and conductors running between a proximal end of the cannula and the electrodes, where the electrodes are at least part of the gas sensor assembly. Lebel further discloses the gas sensor comprising electrodes (elements 36) on a substrate (element 30), with conductors that are used to connect the electrodes to proximal portions of the sensor (elements 44). Lebel does not disclose the substrate being flexible (that is, the sensor assembly being a flex circuit).

Cheney discloses forming a gas sensor assembly using a flex circuit (element 10) comprising a distal portion with two electrodes (elements 24) and conductors (elements 14) connecting the electrodes to a proximal portion of the device (figure 1), so that the sensor is both accurate and durable. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel in view of Markle and Webber with a flex circuit for sensing gas, as taught by Cheney, so that the sensor is both accurate and durable.

Regarding claims 57 and 58, Lebel further discloses a sealed chamber in the cannula containing an electrolyte solution and the electrodes (paragraph [0054]-[0056]).

Regarding claim 60, Cheney further discloses the proximal portion of the flex circuit serving as a connector (elements 26), in order to reduce the number of components and electrical connections in the system. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the probe of Lebel in view of Markle, Webber, and Cheney with the proximal end of the flex

Art Unit: 3735

circuit serving as the connector, as taught by Cheney, in order to reduce the number of components and connections in the system.

Regarding claim 61, Lebel further discloses the electrodes being pads formed on the exposed surface of the circuit (figure 2A).

5. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle, Webber, and Cheney, as applied to claims 56-58 and 60-61 above, and further in view of Schulman (US Patent Application Publication 2001/0051768).

Lebel in view of Markle, Webber, and Cheney discloses all the elements of the claimed invention, as described above, except for the probe further comprising a second sealed chamber housing two additional electrodes and an electrolyte solution.

Schulman teaches an implantable probe for sensing components of blood comprising a plurality of sealed chambers (in this case, the combination of a “sensor assembly” and window), each having two electrodes (elements 12, 14, 16, 18) and an electrolyte solution (element 22) (paragraphs [0026]-[0027], 0031, [0034-0037], [0062]), in order to allow sensing from a variety of areas within the patient’s body without requiring multiple probes. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel in view of Markle, Webber, and Cheney with an additional chamber having electrodes and an electrolyte solution, as taught by Schulman, in order to allow sensing from a variety of areas within the patient’s body without requiring multiple probes.

Art Unit: 3735

6. Claim 62 rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle, Webber, and Cheney, as applied to claims 56-58 and 60-61 above, and further in view of Pantages (US Patent Application Publication 2001/0029337).

Lebel in view of Markle, Webber, and Cheney discloses all the elements of the claimed invention, as described above, except for the probe comprising adhesive to hold the flex circuit in place in the cannula. Pantages teaches an implantable blood characteristic probe comprising a flex circuit held in place in a cannula using adhesive (paragraph [0084]), in order to ensure that the flex circuit does not move. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the probe of Lebel in view of Markle, Webber, and Cheney with adhesive securing the flex circuit within the cannula, as taught by Pantages, in order to ensure that it does not move.

7. Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle and Webber, as applied to claims 25, 26, 28, 29, 63, 64, 68, and 69 above, and further in view of Kirsch (US Patent 6503225).

Lebel in view of Markle and Webber discloses all the elements of the claimed invention, as described above, except for the gas permeable material being polymethylpentene. Kirsch teaches an implantable probe system having a gas permeable coating of polymethylpentene (column 4, lines 43-45), since use of polymethylpentene as a gas permeable polymer coating is well known in the implantable probe art. It would have been obvious to one of ordinary skill in the art at

Art Unit: 3735

the time the invention was made to have made the probe of Lebel in view of Markle and Webber with a polymethylpentene coating, as taught by Kirsch, since it is a well-known gas permeable polymer coating material.

8. Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle, Kirsch, and Webber.

Lebel discloses a probe comprising a cannula (element 12) with proximal (element 14) and distal (element 18) extremities, where the distal extremity is adapted to be inserted in a patient's blood vessel (paragraph [0030]) and contains an oxygen sensor assembly that provides an electrical signal when the cannula is disposed in the blood (element 20; paragraphs [0030], [0032]), and where the proximal extremity carries a connector (element 16); the distal extremity is adapted to slidably travel through an introducer when being inserted into the vessel (figure 9; step 110; paragraphs [0058]-[0059]), and the cannula and connector are sized such that the introducer may be slid off the proximal extremity and cannula after the distal extremity has been inserted (figure 9; step 112; paragraphs [0058]-[0059]). Lebel does not teach the gas sensing assembly comprising both oxygen and carbon dioxide sensors, the area in that vicinity being composed of polymethylpentene, nor the assembly comprising a tube, first and second electrodes, first and second conductors extending through the cannula to the connect to the electrodes in the sensing assembly, and the tube comprising a conduit for one electrode and a support for the other.

Markle teaches a probe for ascertaining characteristics of blood comprising a catheter and a plurality of gas sensors, including those for carbon dioxide and oxygen in the distal extremity of the cannula (column 6 lines 1-3), in order to accurately monitor a patient's blood characteristics. Kirsch teaches an implantable probe system having a gas permeable coating of polymethylpentene (column 4, lines 43-45), since use of polymethylpentene as a gas permeable polymer coating is well known in the implantable probe art.

Webber teaches a sensor assembly for ascertaining blood characteristics comprising a distal sensor and conductor (element 81) within a tube (glass insulation - column 5, lines 32-35) and a proximal sensor extending around the tube (element 82; figure 11), as well as connectors extending through the device (see the left/distal end of figure 11, showing the connectors 81 and 82) in order to conserve space in the device.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the probe of Lebel with an additional gas sensor for oxygen, as taught by Markle, in order to simultaneously monitor multiple components of blood, with a polymethylpentene coating, as taught by Kirsch, since it is a well-known gas permeable polymer coating material, and further including a distal sensor and conductor within a tube and a proximal sensor extending around the tube, as taught by Webber, in order to conserve space in the device.

Art Unit: 3735

9. Claims 71-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle, Kirsch, and Webber, as applied to claim 70 above, and further in view of Cheney.

Regarding claim 71, Lebel in view of Markle, Kirsch, and Webber discloses all the elements of the claimed invention, as disclosed above, except for the probe comprising a flex circuit extending through the cannula, having a distal portion with two electrodes, and conductors running between a proximal end of the cannula and the electrodes, where the electrodes are at least part of the gas sensor assembly. Lebel further discloses the gas sensor comprising electrodes (elements 36) on a substrate (element 30), with conductors that are used to connect the electrodes to proximal portions of the sensor (elements 44). Lebel does not disclose the substrate being flexible (that is, the sensor assembly being a flex circuit).

Cheney discloses forming a gas sensor assembly using a flex circuit (element 10) comprising a distal portion with two electrodes (elements 24) and conductors (elements 14) connecting the electrodes to a proximal portion of the device (figure 1), so that the sensor is both accurate and durable. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel in view of Markle, Kirsch, and Webber with a flex circuit for sensing gas, as taught by Cheney, so that the sensor is both accurate and durable.

Regarding claim 72, Cheney further discloses the proximal portion of the flex circuit serving as a connector (elements 26), in order to reduce the number of components and electrical connections in the system. It would have been obvious to

Art Unit: 3735

one of ordinary skill in the art at the time the invention was made to have made the probe of Lebel in view of Markle, Kirsch, Webber, and Cheney with the proximal end of the flex circuit serving as the connector, as taught by Cheney, in order to reduce the number of components and connections in the system.

Regarding claim 73, Lebel further discloses the electrodes being pads formed on the exposed surface of the circuit (figure 2A).

Response to Arguments

10. Applicant's arguments filed 11 June 2008 have been fully considered but they are not persuasive.

Regarding Applicant's argument that Markle does not disclose an external diameter, the Examiner disagrees, since Markle clearly states that the device has "a maximum external diameter of about 500 microns" (column 5, lines 62-63).

In response to applicant's argument that Markle's motivation of fitting into small vessels is not why the present application was designed, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In response to applicant's argument that Kirsch is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was

Art Unit: 3735

concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Kirsch is reasonably pertinent, being directed to a device that is implanted in blood and concerned with finding blood-compatible materials.

Applicant has also argued that Webber does not disclose all the limitations of claim 25; the Examiner agrees, but notes that Webber is used in a combination and the other references in the combination have the feature at issue. The mere fact that Webber alone does not disclose all the limitations does not preclude it from being obviously combinable with other references.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patents 4861454 to Ushizawa, 5165407 to Wilson, and 6965791 to Hitchcock, and US Patent Application Publication 2004/0111141 to Brabec, which disclose similar inventions.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone

Art Unit: 3735

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735